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1632

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	FAUSTMAN, Denise L.	
Serial No.:	09/673,292	ART UNIT: 1632
Filed:	October 13, 2000	EXAMINER: WEHBE, A.S.
Entitled:	TRANSPORTER PROTEIN SPLICE VARIANTS AND MODEL FOR IMMUNE DIVERSITY	

Atty. Docket No.: MGH-002.1P US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith are: [X] Response to Election/Restriction Requirement; and [X] a return postcard.

FEE FOR ADDITIONAL CLAIMS
[X] A fee for additional claims is not required.
[ ] A fee for additional claims is required. The additional fee has been calculated as shown below:

	TOTAL CLAIMS	HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER OF EXCESS CLAIMS	RATE	FEES DUE
TOTAL CLAIMS	---	---	0	× $---	= 0.00
INDEPENDENT	---	---	0	× $---	= 0.00
FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM				+$---	= 0.00
TOTAL FEES DUE					= **00.00**

[X] Small entity status has already been established for Applicant(s) in this case.

PAYMENT OF ADDITIONAL FEES

[ ] A check in the amount of $ 00.00 in payment of the fee for additional claims is transmitted herewith.

[ ] A check including the amount of $ 00.00 in payment of the fee under 37 CFR §1.18(a) for issuing an original patent.

[X] The Commissioner is hereby authorized to charge payment of any additional fees required under 37 CFR 1.16 or 1.17 in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268 . A duplicate copy of this transmittal letter is transmitted herewith.

PETITION FOR EXTENSION OF TIME

[ ] Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the paper(s) filed herewith: [ ] $55.00 for response within first month pursuant to 37 CFR 1.17(a)(1);
[ ] $205.00 for response within second month pursuant to 37 CFR 1.17(a)(2);
[ ] $465.00 for response within third month pursuant to 37 CFR 1.17(a)(3);
[ ] $725.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4).
[ ] $985.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).

[X] Total amount of payment in connection with the paper(s) transmitted herewith is $ 00.00.
{check no. --}

[X] The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268 .

Respectfully submitted,

Leon R. Yankwich; Registration No. 30,237
Michael R. Wesolowski; Registration No. 50,944
Applicant's Representatives
YANKWICH & ASSOCIATES
201 Broadway
Cambridge, Massachusetts 02139
telephone: (617) 374-3700
telefax: (617) 374-0055

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September 2, 2003
date


Stephanie Leicht

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	: FAUSTMAN, Denise L.
Serial No.	: 09/673,292
Filed	: October 13, 2000
Entitled	: TRANSPORTER PROTEIN SPLICE VARIANTS AND MODEL FOR IMMUNE DIVERSITY

ART UNIT: 1632

EXAMINER: WEHBE, A[illegible]S

Atty. Docket No.: MGH-002.1P US

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P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This paper is filed in response to the Office Action dated July 30, 2003. The one-month shortened statutory period for reply expired August 30, 2003 (Saturday). This paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on Tuesday, September 2, 2003. Because Monday, September 1, 2003 was a Federal Holiday (Labor Day), no fees are believed to be due with this filing; however, the Commissioner is specifically authorized to charge any fees deemed to be necessary in connection with the filing of this paper to Deposit Account 50-0268.

In the Office Action, a restriction of Applicant's invention has been required, as between:

Group I	(Claims 1-23 and 31-32) drawn to nucleic acids encoding TAP splice variants, vectors encoding said nucleic acids, host cells transformed with said vectors, methods of producing polypeptides using said host cells, and methods of altering peptide transport in a cell using said nucleic acids;
Group II	(Claims 24-28) drawn to TAP splice variant polypeptides; and
Group III	(Claims 29-30) drawn to antibodies recognizing TAP variants.

The Examiner reasons as follows:

> "The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related in part as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §806.05 (f)). In the instant case, the polypeptides of invention II can be made by using an amino acid synthesizer, or by isolating said naturally occurring polypeptides from human cells.
>
> Inventions I-III are further patentably distinct in that the nucleic acids, vectors and host cells of invention I, the polypeptides of invention II, and the antibodies of invention III have substantially different structures and properties, are made using substantially different effects, and can be used for substantially different purposes." (Office Action, pages 2-3.)

Applicant notes that the Examiner has repeated the restriction verbatim from the parent case, application Ser. No. 09/061,764, now U.S. Patent No. 6,284,879. The present application, however, is a continuation-in-part of the parent case and therefore contains different and additional claims from its parent application, e.g., the present application was filed with 42 claims, not 32. Despite the inconsistency, and although Applicants do not acquiesce to the reasoning, it is clear that the same restriction grouping may be applied to the present claim set, with Claims 1-30, 40, 41, and 42 falling into Group I, Claims 31-36 falling into Group II, and Claims 37-39 falling into Group III. The present paper answers the Office Action as if such a grouping of the original claims had been made.

Applicant traverses this requirement and requests consideration of all claims together in this application for the reasons set forth below.

The present invention relates to the discovery of previously unknown isoforms homologous to the known TAP protein subunits. The newly discovered isoforms are the result of alternate RNA splicing and are co-expressed with the known TAP1 and TAP2 gene products, providing a plurality of TAP heterodimers functioning to translocate antigen peptides from the cytoplasm into the endoplasmic reticulum for complexing with MHC class I molecules and formation of MHC class I antigen complexes. The splice variant isoforms have been found to form TAP heterodimers that transport a different repertoire of peptides or that transport similar peptides at different rates than the known TAP1/TAP2 heterodimer. The discovery of these alternative TAP transporter proteins exposes a genetic mechanism of diversification in the process of MHC class I antigen presentation. Co-expression of multiple TAP1

and TAP2 splice variants provides a diverse family of transporters capable of translocating a wider range of antigen peptides from the cytosol to the ER and increasing the repertoire of MHC class I antigen complexes presented to the immune system. It is through such diversification mechanisms that it is now demonstrated that the antigen processing and presentation mechanisms of the immune system are able to drive and select T cell response diversity of the recognition side of the immune system, which is based on the enormous diversity of the T cell receptor. More specifically, the present invention raises the possibility that a deletion of defect in expression of a particular TAP1 or TAP2 isoform, or that an abnormal expression level of one TAP1 or TAP2 isoform with respect to another, may cause the manifestation of autoimmune disease.

The Examiner's original grouping of the claims indicates that each of the practical embodiments of the above discovery described in the application and recited in the claims have been regarded as a separate invention that must be prosecuted separately. However, because the embodiments of the invention share common features, fractionation of the claims as required in the Office Action would lead to unnecessarily repetitive examination and an unfairly protracted and expensive series of related applications to be filed by Applicant to obtain the patent protection to which she is entitled. Moreover, they are not unrelated methods and products; they are all methods and products that stem from the link discovered between the existence of splice variants of transporter associated with antigen processing, or TAP, proteins and the education of the immune system, i.e., proper MHC class I antigen processing and presentation.

In view of these common features, it is seen that all of the claimed polynucleotides, polypeptides, antibodies and methods of use may be efficiently searched together, without placing an undue burden on the Examiner. Applicant submits that the search of any of the claim groups, Groups I, II or III would necessarily reveal the same art that is relevant to the other groups, and therefore no additional search will be required if a restriction is not made. Instead, the burden will be on the Applicant, who will be required to increase her expenses to address the same search before full patent protection of the original invention is obtained.

Conclusion and Provisional Election

Applicant submits that in view of the foregoing remarks all the claims as originally filed are seen to relate to a single inventive concept, and the claims are in a form and are of the sort that is properly

viewed as relating to a single invention that should not be restricted. Applicant therefore requests that the restriction requirement of the Office Action of July 30, 2003 be reconsidered and withdrawn.

Although, for reasons set forth above, Applicant believes that the restriction is improper and uncalled for, and without in any way acquiescing in the reasons for the requirements set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicant provisionally elects for examination the claims of Group I, i.e., Claims 1-30, 40, 41, and 42.

Respectfully submitted,

Michael Wesolowski

Leon R. Yankwich, Reg. No. 30,237
Michael R. Wesolowski, Reg. No. 50,944
Applicant's Representatives
YANKWICH & ASSOCIATES
201 Broadway
Cambridge, Massachusetts 02139
telephone: 617-374-3700
telecopier: 617-374-0055

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Stephanie Leicht
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